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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,442	04/13/2001	John S. Whitaker	29342/37225	2950

7590 09/09/2002

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EXAMINER
BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER
	8

DATE MAILED:

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Commissioner of Patents and Trademarks

Per discussion with applicant's attorney on 09/04/02 and recommendation by Bill Dixon, SPRE the action attached hereto is being remailed and the period of time restarted since the applicant did not receive the final rejection.

Office Action Summary	Application No.	Applicant(s)	
	09/834,442	WHITAKER ET AL.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendments and response to the first office action of August 15, 2001, submitted December 19, 2001 (Paper No. 7) is acknowledged.

Applicant' amendment and arguments have overcome the objections in the previous office action. Applicant's argument concerning the specie election requirement has been persuasive and the search has been extended to include vardenafil and sildenafil of claim 12.

Claims 1-13 have been examined on the merits herein in so far as they read on the elected species.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3,6-8, 13-17 of copending Application No. 09/558911. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference in the two applications is the package insert and the dosage.

The optimization of amounts are within the skill of the artisan and are therefore obvious. Moreover, the inclusion of a package insert including "indications and use" of the pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art. (See *Remington's: the Science and Practice of Pharmacy*, Nineteenth Edition, Vol. 1, page 806). Further, the particular package insert precautions herein are motivated by the prior art since selective PDE5 inhibitors would have been reasonably expected to exhibit the therapeutic activity for treating erectile dysfunction known for PDE5 inhibitors, while at the same time producing additional or reduced side effects related to interaction with other additional receptors.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daugan et al. (WO 96/32003) in view of the abstract of Neiwohner et al. (WO 99/24433), both of record in the previous office action.

Daugan et al. (WO 96/32003) teaches a pharmaceutical composition comprising a PDE-5 inhibitor compound of formula I, see abstract. Daugan et al. (WO 96/32003) teaches that its pharmaceutical composition can be used to treat erectile dysfunction, see particularly page 7, line 34 and page 8 line 1. Daugan et al. (WO 96/32003) shows that the compounds of formula I exhibit an IC50 value of less than 10 nM, see particularly Table 1. Daugan et al. (WO 96/32003) also teaches that the preferred route of administration is oral, and that the dosage range is from 0.5-800 mg, individual tablets contain from 0.2-400 mg of the active compound in a suitable pharmaceutically acceptable carrier, for administration in single or multiple doses, once or several times per day (which may constitute chronic administration), see particularly page 9, lines 5-11. Daugan et al. (WO 96/32003) also teaches that its pharmaceutical composition can be used in treating cardiovascular disorders, e.g. conditions of reduced blood vessel patency, peripheral vascular disease, see particularly page 7, lines 21 to page 8, line 2.

Daugan et al. (WO 96/32003) does not teach the inclusion of a package insert or a container.

Neiwohner teaches 2-phenyl substituted imidazotriazinones (including vardenafil) are suitable for use as active agents in medicaments for treating cardiovascular and cerebrovascular diseases, see abstract and example 19.

It would have been obvious to one of ordinary skill at the time the invention was made to include the PDE-5 active herein in a container and to include the package insert herein for the therapeutic composition.

One of ordinary skill in the art would have been motivated to include the therapeutic agent comprising PDE5 in a container since the packaging of pharmaceutical compositions is widely practiced in the art and is therefore within the skill of the artisan. Moreover, the inclusion of a package insert including "indications and use" of the pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art. (See *Remington's: the Science and Practice of Pharmacy*, Nineteenth Edition, Vol. 1, page 806).

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/03675 (submitted by the applicant in the parent application 09/558911, August 29, 2001), in view of Viagra prescribing information (of record in the parent application)Neiwohner, *Remington: The Science and Practice of Pharmacy* (of record in the previous office action).

WO 97/03675 teaches the instant compound in an article useful in treating erectile dysfunction in a dose of 0.5-800 mg/day, see abstract and page 5 in particular.

WO 97/03675 does not teach the employment of vardenafil or sildenafil, the inclusion of a package insert, nor does it disclose a container.

Viagra prescribing information teaches sidenafil as a PDE5 inhibitor. It also teaches that Viagra is packaged in bottles of 30-100 pills.

Neiwohner teaches 2-phenyl substituted imidazotriazinones (including vardenafil) are suitable for use as active agents in medicaments for treating cardiovascular and cerebrovascular diseases, see abstract and example 19.

It would have been obvious to one of ordinary skill at the time the invention was made to include the PDE-5 actives herein in a container and to include the package insert herein for the therapeutic composition.

One of ordinary skill in the art would have been motivated to include the therapeutic agent comprising PDE5 herein in a container since the packaging of pharmaceutical compositions in articles is widely practiced in the art and is therefore within the skill of the artisan. Moreover, the inclusion of a package insert including "indications and use" of the pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art. (See *Remington's: the Science and Practice of Pharmacy*, Nineteenth Edition, Vol. 1, page 806).

Different responses to different regimens of PDE5 inhibitors are shown on pages 36-37 of the specification. These tables illustrate no unexpected results because an increased response would have been reasonably expected with more frequent administration of the active. Sildenafil, is known to be useful in an article of manufacture in the doses herein and packaged in a container.

Response to Arguments

Applicant's first remark that formula I compounds disclosed in the cited prior art WO '003 is not exactly the same as the compound disclosed in the claims. Note that none of the claims examined on the merits in the application at the time of the prior office action recited a chemical formula as a limitation. Moreover, note that the only difference between the formula I compound of WO'003 and the claimed structure in claims 13 is the substitution of a six-membered ring for a five-membered ring in the claimed structure. The substitution of a six-member ring for a five-member ring in the claimed structure will result in two very structurally similar compounds and one of ordinary skill in the art would expect structurally similar compounds to exhibit similar therapeutic effects in treating erectile dysfunction, see MPEP 2144.08 (J), 2144.09, see also *In re Hoch*, 166 USPQ 406.

Applicant also argues that a chronic dosing regimen for at least three days is not taught by the prior art. Note that the instant claims are not method claims, they are claims drawn to a product/article of manufacture. The recitation of a dosage regimen in a package insert attached to an article of manufacture does not further limit a claim drawn to an article of manufacture.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
March 1, 2002